DESIGN OF AN AMGEN TRASTUZUMAB MANUFACTURING FACILITY TO CONTINUOUSLY PRODUCE KANJINTI, A HER2+ BREAST CANCER TREATMENT BIOSIMILAR

AN EXAMINATION OF THE EVOLUTION OF ACCOMMODATIONS OF NEURODIVERSE STUDENTS IN US PUBLIC EDUCATION

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By

Joseph Letteri

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SOCIOTECHNICAL SYNTHESIS

The ability to abstract information using our powers of observation, contemplation, and action has enabled the human race to create a society that strives to ethically balance the generation of fierce competition for innovations with the continuous maintenance of humans' right to life, liberty, and the pursuit of happiness. Cancer severely decreases a person's quality of life by causing a slow and painful death. The intersection of academically inspired research and corporate driven ideologies led to the creation of targeted breast cancer therapeutic trastuzumab, and increasing access to such treatment serves to benefit myriads of people. Such innovation requires efficient and distributed investment in human capital, especially through the design and continuous evaluation of social institutions such as healthcare and education. Increasing access to both trastuzumab for cancer patients and effective accommodations for students with learning differences in United States public education require the utilization of continuous processes to produce constant, targeted solutions.

A continuous bioprocess using upstream and downstream technologies demands the use of human capital for its both design and operation. Successful operation of such a bioprocess would not only increase access to its product, but also alleviate human capital affected by the devastation of cancer. Modeling of cell growth and protein production can be done in conjunction with critical parameters such as temperature, power, and oxygen transfer to determine optimal bioreactor conditions. Using a perfusion reactor with tangential flow filtration allows for cell recycle, and therefore continuous 30-day operation. Downstream operations utilize membrane- and chromatography-based separations enables a purified product that meets FDA standards. Single-use materials are

employed for the bioreactor, tubing, and buffer holding to reduce costs and waste produced.

The proposed Kanjinti manufacturing process would reduce the cost of treatment by more than 18% compared to the name-brand Herceptin treatment. By lowering the price of treatment, it is expected that Amgen would capture 17% of the global trastuzumab market by producing 111.7 kg of Kanjinti each year. It is recommended that Amgen moves forward with the proposed project. Given the consistent high demand of trastuzumab, this manufacturing facility will be a feasible in its goal of increasing access to high-quality cancer treatment and ensuring a financially viable long-term investment.

An efficient and equitable public education system is essential for effective investment in human capital for any nation. Currently, the US ranks relatively low compared to other modernized nations in terms of human capital investment in healthcare and education. Unbalanced influences and poor communication between influential social groups can prevent students with learning differences from accessing individualized and functional accommodations. The theory of social construction of technology provides a framework to evaluate the evolution of accommodations, and suggests that flaws in social groups that create the provision of such accommodations can be greatly mitigated through renovations that allow for constant communication between medical researchers, educators, and policy makers. Carefully reviewed research in the past couple decades proves rigorous mentoring, early social interventions, and further advocacy of accessibility and support groups for students with learning differences can reveal unprecedented human capital for the United States.

In conclusion, renovating society's constituents through continuous collaboration of social and physical systems will allow said constituents to experience a greater quality of life. Investing in continued collaboration will enable improved access to proven solutions and allow society to flourish in higher excellence.

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